MANUFACTURING & LABELING CHECKLIST
FOR LOW & MODERATE RISK FOODS - PROCESS REVIEW INFORMATION

RETURN TO: MONTANA FOOD, DRUG & COSMETIC PROGRAM
COGSWELL BLDG RM C214
PO BOX 202951
HELENA MT 59620-2951
Phone (406) 444-5306

The following questions should be answered about your product. If the question does not apply to your particular product write "N/A" and if not obvious, then tell why it does not apply. If you have questions about the meaning of some questions please feel free to call us at the above number. Low risk foods include dry mixes, berry preserves, syrups, confections, baked goods, mustards, etc.

NAME OF MANUFACTURING/PROCESSING ESTABLISHMENT

NAME OF OWNER CORPORATION

CONTACT PERSON ___________________________ EMAIL, IF ANY ___________________________

STREET ADDRESS OF POINT OF MANUFACTURE

________________________________________

MAILING ADDRESS (if different) _____________________________________________________

CITY ___________________________ STATE ______ ZIP ____________

TELEPHONE # (_____) - ___________________ FAX # (_____) - ___________________

IS THIS PRODUCT INTENDED TO BE A: (Check one)
FOOD PRODUCT______ DIETARY SUPPLEMENT______ COSMETIC______ DRUG / MEDICATION______

COMMON NAME FOR THE PROPOSED PRODUCT _________________________________________

(i.e. - "Pancake mix")

YOUR TRADE NAME FOR THE PRODUCT ______________________________________________

(i.e. - "Blue Mountain Buckwheat Pancake Mix")

IS THE PROCESSING CONFINED TO REPacking? _______ YES _______ NO (Rpacking is a process in which large containers of food are repacked into retail size packages, i.e. 100# sacks of beans repacked as 1# packages.

WILL THERE BE ONSITE RETAIL SALES? _______ YES _______ NO

WILL THE PRODUCT BE SOLD WHOLESALE (case lots) FOR RE-SALE ELSEWHERE? _______ YES _______ NO

WHAT STORES WILL BE CARRYING THE PRODUCT ______________________________________

WILL THE PRODUCT BE SOLD VIA THE INTERNET? _____________________________

WILL THE PRODUCT BE SOLD ONLY IN MONTANA? _______________ OUTSIDE MONTANA (INTERSTATE) ________
**Batch Size**

**Batch Weight**

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<th>Ingredient</th>
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List all components that have ingredients within the ingredients in parentheses:

*Mayonnaise (egg yolks, vegetable oil, lemon juice, salt, vinegar, oxystearin...)*

(A copy of page 2 is needed for each variation, including label exhibit. For example—one set for blueberry muffins, and another set for poppyseed muffins, and another for brownies, etc. Photocopy p. 2 as needed.)

Are any restricted ingredients to be used or already in your product (Sulfites, sweeteners, MSG flavorings)?

YES  NO

List here:

List all food colorings, whether added directly or contained within ingredients used in the product (ingredients within ingredients).

Are any organic claims being made?

YES  NO  IF YES, THEN ATTACH 3rd PARTY CERTIFICATION COPIES OR OTHER DOCUMENTATION.

Are any other claims being made such as "pure", "natural", "light", "low cholesterol", "low fat", "reduced salt", etc?

YES  NO  IF YES, THEN ATTACH DOCUMENTATION.

If a nutritional claim is made, you may not use the exemption from nutrition facts labeling.

Is nutritional labeling information being included?

YES  NO  IF YES, THEN ATTACH DOCUMENTATION, OR EXPLANATION.

Note: Nutrition labels required after May 1994, with some exceptions - including small business producing less than 10,000 units last year and having fewer than 50 employees, if no label claims are made or implied. For further description of NLEA exemption see pp. 22-28 of the LABELING GUIDE, or call us at the number given above.

Will the product label require refrigeration?

YES  NO

Will there be an "out date" or "best if used by ..." date?

YES  NO

If the product is to be wholesaled (offered at outlets away from the manufacturing facility, include information on what quality control procedures you will use.)
MANUFACTURED FOOD SECTION

LOW ACID CANNED FOODS 1) Have pH greater than 4.6 and water activity greater than 0.85, 2) are sealed hermetic (air-tight) container, 3) receives a heat treatment for the purpose of achieving commercial sterility, 4) and is normally stored under non-refrigerated conditions.

AN ACIDIFIED FOOD is a low acid food to which acid(s) or acid food(s) are added. It has a water activity greater than 0.85 and a finished equilibrium pH of 4.6 or below. An acidified food is normally stored and distributed under non-refrigerated conditions. (Carbonated soft drinks are not acidified foods.)

IF YOU MEET EITHER OF THE ABOVE CRITERIA YOU MUST HAVE AN FDA APPROVED SCHEDULED PROCESS, APPROPRIATE TRAINING, AND YOU MUST REGISTER YOUR PRODUCT WITH THE FDA (FOOD & DRUG ADMINISTRATION). IF APPLICABLE ARE YOU REGISTERED WITH FDA?

N.A. ______ YES ______ NO ______

IF ACIDIFIED FOODS OR LOW-ACID FOODS ARE TO BE PRODUCED & PACKAGED, INCLUDING SALSA, DRESSINGS, SAUCES ETC., WITH A pH OF 4.5 OR ABOVE YOU SHOULD USE THE MONTANA PROCESS SCHEDULE FP114. INCLUDE LAB TEST RESULTS FOR pH.

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DESCRIBE IN DETAIL YOUR MANUFACTURING PROCESS: INCLUDE TIMES, TEMPERATURES OF COOKING PROCESS IF APPLICABLE, SOURCE OF PRINCIPAL INGREDIENTS & ALSO DESCRIBE SET UP PROCEDURES, FINISHED PRODUCT HANDLING, CLOSURES, PRODUCTION CODES OR DATE CODES, SHELF LIFE, QUALITY CONTROL OR TESTING PROCEDURES ETC. (Use additional sheets if necessary)

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PACKAGING MATERIAL, CONTAINER CLOSURES: (describe)
LABELS - MOST COUNTIES REQUIRE LABELING REVIEW & APPROVAL PRIOR TO LICENSING. AN ACTUAL SIZE LABEL EXHIBIT IS NEEDED FOR THIS PURPOSE. A CLEAR PHOTOCOPY WILL DO.

ATTACH PRINTERS PROOF OR PHOTOCOPY OF PROPOSED LABEL HERE, OR ON A SEPARATE SHEET.

IF THIS IS A NEW FACILITY, HAVE YOU CONTACTED THE LOCAL HEALTH DEPARTMENT FOR APPROVAL AND INSPECTION OF YOUR FACILITY? YES ____ NO ____

NAME OF THAT DEPARTMENT __________________________________________________________

WHO DID YOU TALK TO THERE _________________________________________________________

DID YOU HAVE A CURRENT "Food Purveyor License" ISSUED BY THE DEPARTMENT OF PUBLIC HEALTH & HUMAN SERVICES (FOOD & CONSUMER SAFETY)? YES ____ NO ____

IF YES, GIVE NAME ISSUED UNDER: ____________________________________________________

AND THE NUMBER OF THE LICENSE: F ________________________________________________

AND THE ENDORSEMENT TYPE (F1, F2, F6, F13 ETC): ______________________________________

AND THE COUNTY IN WHICH LICENSE WAS ISSUED: _________________________________________

AND THE PRODUCT CODES APPROVED (IF ANY): __________________________________________
WATER BOTTLERS

IF YOUR PRODUCT IS WATER, HAVE YOU CONTACTED THE DRINKING WATER PERMIT SECTION OF THE MONTANA DEPARTMENT OF ENVIRONMENTAL QUALITY (DEQ)?

YES _____ NO _____ N/A _____

DATE __________ CONTACT PERSON __________________________

HAVE PLANS BEEN SUBMITTED TO THAT AGENCY AND APPROVED?

YES _____ NO _____ PWS NUMBER ISSUED ______________________

DESCRIBE THE SIZE OF CONTAINERS OR BOTTLES YOU WILL BE USING: ________________________________

PRIOR APPROVAL AND A PWS NUMBER ARE REQUIRED PRIOR TO LICENSING. PRODUCTION CODING/DATE CODING ARE REQUIRED FOR BOTTLED WATER.

INCLUDE A SCHEMATIC OF THE WATER TREATMENT, CONTAINER STORAGE PLANS, BOTTLING EQUIPMENT, LABELS, COPIES OF THE CHEMICAL ANALYTICALS, AND OTHER DETAILS AS ATTACHMENTS TO THIS FORM.

IF YOU ARE PACKING OR BOTTLING WATER FROM A SOURCE OTHER THAN YOUR OWN (CO-PACKING FOR ANOTHER FIRM) THE ANALYTICALS FOR THEIR WATER MUST BE REVIEWED AND APPROVED PRIOR TO BOTTLING. IF YOU ARE BOTTLING YOUR WATER UNDER DIFFERENT SPONSOR LABELS, PLEASE INCLUDE LABEL EXHIBITS AS APPROPRIATE.